UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NUMBER: 19-md-02875**
	CASE MANAGEMENT CONFERENCE via ZOOM VIDEOCONFERENCE

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
July 13, 2022
Commencing at 4:03 p.m.

B E F O R E: **THE HONORABLE THOMAS I. VANASKIE (RET.)**
SPECIAL MASTER

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(PROCEEDINGS held via Zoom before and SPECIAL MASTER THOMAS I. VANASKIE at 4:03 p.m.)

SPECIAL MASTER VANASKIE: All right. I guess we can get started. I don't hear anybody ringing in right now.

There it goes. Always happens. I'll wait five minutes and I start talking and it will ring.

All right. We have our discovery conference. Looks like it should be a relatively brief conference.

And who will be the spokesperson for the plaintiffs on this call?

MR. HONIK: Good afternoon, Your Honor, Ruben Honik appearing. You'll be hearing from me as well as Ms. Goldenberg.

SPECIAL MASTER VANASKIE: All right. Great. Thanks. Thanks, Mr. Honik.

Who will be the spokesperson for the defense?

MS. BROWN: Good afternoon, Your Honor. This is Alli Brown for ZHP. I'll be addressing one of the issues, and then my colleague Rich Bernardo will be addressing another. And then I think we have one or two other members of the defense, joint defense group, that will address the third issue.

SPECIAL MASTER VANASKIE: All right. Very well.

MS. BROWN: And Your Honor, if I could trouble you and everyone else, would it be possible to start with the case management -- the request for the case management order? Only

because I'm going to address that, and I'm afraid I can't stay on as long as this may go.

SPECIAL MASTER VANASKIE: Yeah, we can address that first.

And you're referring to Case Management Order 28?

MS. BROWN: Correct, Your Honor.

SPECIAL MASTER VANASKIE: Judge Kugler has informed me that he has no problems with respect to that order, and it was my intention to immediately after this conference call send it down to Larry to be docketed --

MS. BROWN: Could I be --

SPECIAL MASTER VANASKIE: -- unless there was some changes to it.

Go ahead.

MS. BROWN: Yeah. If I could be heard on that, Judge, that would be terrific.

This initial request for the discovery contained in the order came out of a letter that plaintiffs sent us in advance of the June 1st conference in front of Judge Kugler.

We had sort of an extensive discussion and argument about just what was being requested. And, you know, Your Honor, one of the things we discussed with Judge Kugler is that we're not necessarily opposed to the concept of discovery. We agree that we need to move these cases forward. We agree discovery in certain circumstances may be needed.

The issue and objection that we raised with Judge Kugler was that plaintiffs had not yet at the time of their request identified the case in which they would be seeking this discovery or the state law under which they would be moving for these potential summary judgment motions.

And what we did, Judge, in our letter in advance of this conference is we cited to you some of the relevant discussions and statements from Judge Kugler.

SPECIAL MASTER VANASKIE: Right.

MS. BROWN: And so, for example, if you see there number 2, Judge, our statement on the proposed case management plan, Judge Kugler, I would submit to Your Honor, was unequivocal when he said that the exact claim on which plaintiffs are seeking summary judgment and the statutes under which they're seeking it need to be identified.

And when we were discussing this schedule, sort of the very schedule that they're talking about here, I had said, Judge, you know, our position is we need to get to a place where they identify a plaintiff and they identify a state law.

And the Judge -- and we cited it here -- said that that was what he intended as well, and that if that didn't happen, he would fix it.

And so we would submit to Your Honor, it's not the discovery per se that we are opposing, it's the failure to identify a case.

And back in June, the Judge had I believe encouraged the parties to perhaps consider a third-party payor case or consider an individual economic loss plaintiff, but he made clear in response to our objection and argument that he understood the controlling case law that we had reviewed, Judge, that you can't of course move for summary judgment in the ether, that we can't move on liability issues untethered to particular claims, to particular plaintiffs, and importantly for the Court, to a particular law.

And I think the Judge was very clear here that he believed the proposal contemplated the identification of a plaintiff and the identification of the law and that that would have to be done to frankly give us our due process rights to be able to request our own discovery and to be able to properly respond to any motions that plaintiffs might file.

So our objection, Judge, is to the form of the order, which respectfully is no different than the letter that we argued in front of Judge Kugler and which Judge Kugler made clear did not sufficiently identify plaintiffs or the state law.

SPECIAL MASTER VANASKIE: What exactly are you proposing, Alli?

MS. BROWN: Sure. Thanks, Judge.

So what I understood coming out of our discussion and coming out of the Court's direction was that plaintiffs were

to let us know the identity of a plaintiff, you know, the case, the named plaintiff and the case, in which they wanted this discovery, first and foremost so that we would know what claims are at issue; importantly for the Court, what law is applicable. And as I understood Judge Kugler, because the case -- the class certification motions are still pending, he was indicating that perhaps the parties wanted to think about a third-party payor class.

We had suggested -- and Judge, to be quite candid, I know Judge Kugler has rejected it, but we had suggested discovery in the context of personal injury plaintiffs. I understand that's not where the Court wants to go.

But coming out of the conference, and certainly we cited it here, what was clear is that he expected, and frankly, controlling law would demand it, that we have the identify of the case and the plaintiff and the law at issue and the claims under which they intend to move.

And if you look at the transcript and the parts we cited here, I think that squares perfectly with what the Judge said would happen, and if it doesn't, we'll fix it.

And so I guess we're just coming to you, Judge, to say, I think this case management order needs a little fixing along the lines of what Judge Kugler talked about on the 1st.

MR. HONIK: Your Honor, may I address it? I think I can resolve the issue that Ms. Brown is bringing up.

SPECIAL MASTER VANASKIE: You certainly may, Mr. Honik.

MR. HONIK: So let me provide a tiny bit of context.

It's correct that this issue came up just exactly as Ms. Brown is setting out. And we have had a number of meet and conferrals about this, and I think we better understand at this point the issue that the defendants have raised. And they're not incorrect.

And so what we are proposing, and in fact what we will be doing, by no later than the beginning of next week, to Ms. Brown's point and request, we will be identifying with specificity the economic class group or subgroup that we intend to pursue dispositive motions on and identify the plaintiffs or class representatives that relate thereto. And in fact, we intend to lay that out in our next letter to the Court so that we can present it to Judge Kugler and actually attach a trial plan. Because after all, what this case management order is about, is simply moving the case forward.

Now, ordinarily, you know, we might have a certain sequence of events. We might have had or may be nearer a cert ruling which may help inform and narrow the issues and so forth. But in the absence of that, I think the case management order as we have proposed it to the Court and discussed at our last conference, which Judge Kugler is prepared to enter, is perfectly fine in its current form,

coupled with the representation we're now making on behalf of the plaintiffs' group, that Ms. Brown and the defendants will have by next week exactly what they have been seeking, which is the identity of one or more class groupings, the class reps who are there, the defendants, in fact, that we propose to pursue against with respect to dispositive motions, and therefore, address all of the issues that Ms. Brown has brought up.

SPECIAL MASTER VANASKIE: All right. Ms. Brown, why don't we proceed on that basis?

Go ahead.

MS. BROWN: Your Honor, thank you very much.

And I appreciate the clarification from counsel. What I would suggest in that instance, Your Honor, is that we not put the cart before the horse here and that we wait to get counsel's representations of the plaintiffs and the law and the claims.

And the reason I say that, Judge, is because counsel said a couple of things that made me nervous in terms of controlling law.

He made some references to class plaintiffs. And of course I don't have to tell Your Honor, the law would prevent this Court from making any rulings on a putative class that has not yet been certified.

And so I think the proper way to go about this,

truthfully, to allow us to properly assess what it is that they're proposing, if we can hold off a week, if we can get the information from counsel, have the opportunity to meet and confer with them on just what their proposal is, and then either come back to you or Judge Kugler if there remains any objections.

And I think there might, based on the little bit of information I just heard. But at this point it's really hard to assess that without that information, Your Honor.

MR. HONIK: Your Honor, I'm at a loss to really understand.

The Case Management Order Number 28 that we've proposed really simply addresses the exchange of expert reports on merits and dispositive motions, putting that on the calendar.

We control our case. We're the plaintiffs. And we will identify those areas and those motions that we intend to file. It doesn't impact putting this on the calendar. And unless Ms. Brown can enlighten the Court and myself and the rest of the plaintiffs precisely how learning who we choose to file or what we choose to file dispositive motions about impacts putting these dates on the calendar, I'm at a loss to understand why Judge Kugler doesn't do what he, I think, is poised to do, which is to enter this order today so that we have it on the calendar and all of us can benefit from knowing

when these various important dates are going to come up.

MS. BROWN: Judge, if I may, I think I could answer that question, if the Court would allow me.

SPECIAL MASTER VANASKIE: Go ahead.

MS. BROWN: Okay. Your Honor, the reason we need to know the plaintiffs and the case and the claims is because we too will seek certain discovery. And the Judge made that clear last time, that this was not going to be a one-way street, where only plaintiffs can pursue discovery, but certainly defendants in defending these cases and in exercising our due process rights would have the ability to have our own discovery.

And so just take, for instance, we started to look at the third-party payor cases, as the Judge sort of encouraged us to do. And there's a host of discovery, Your Honor, that we would need -- and frankly, we raised this with counsel on a meet and confer -- that we would need in some of those cases, to be able to respond, to have responsive expert reports, to be able to defend against those motions.

And so before we put a schedule in place that we have no idea what the plaintiff is, we have no idea what the law is, we need to know that information so that we can propose our own part of this case management order that would allow for the very same equal discovery that Judge Kugler indicated was appropriate on our last conference.

MR. HONIK: Your Honor, I'm --

SPECIAL MASTER VANASKIE: Let me ask a question, please, Mr. Honik. All right?

MR. HONIK: Sure.

SPECIAL MASTER VANASKIE: You were going to answer it with what you were about to say, so we'll see. We'll see if we're on the same wavelength.

But what would be inappropriate -- and I'm asking this question of Ms. Brown now.

What would be inappropriate about entering this order and then taking up at our next case management conference some of these matters that you've talked about in terms of fleshing out the order? In other words, this is the skeleton. Now we're going to hang some skin on the skeleton, put some muscle on it, et cetera, to flesh it out. Bad analogies. But what I'm trying to indicate is we have a framework here that sets up a schedule, and then we can fill in that framework.

What would be wrong with that?

MS. BROWN: Well, Your Honor, I believe that was the very subject of the argument in front of Judge Kugler in early June, because the schedule that they've submitted here for signature and entry is the very proposal that was the issue in front of Judge Kugler. It's the very proposal we objected to, because frankly, it's contrary to law, to allow this type of expert liability, expert discovery, liability, Daubert

motions. It contravenes controlling law which says you can't address liability in the ether without a complete cause of action, without the causation and the damages.

And we made the argument and we cited the cases to Judge Kugler who agreed. And he, you know, was quite clear on the record, that is not what was going to be done here. We were not going to have what's being asked for in this case management order.

And so I would submit the proper way to proceed is to at least allow us the opportunity to understand what Judge Kugler said the plaintiffs would provide us with, which is the plaintiff, the state, the claims, give us an opportunity to just have that information, and then we can meet and confer on what we believe would be a proposed -- an appropriate schedule.

But my objection, Judge, is that the proposed order was the subject of the hearing in front of Judge Kugler, and Judge Kugler said that plaintiffs would have to identify plaintiffs and law before we could proceed.

MR. HONIK: Respectfully, Your Honor, the Judge did not say that that was a requirement before imposing a schedule. And no one is proposing that there should be a summary judgment ruling or I dare say a trial on the merits before certification. No one is proposing that at all. But what we're trying to do is to honor what the Court has asked

us to do, which is to move the case forward.

Class cert is fully briefed. Whenever the Court should deign to rule on that, that's fine. But we took Judge Kugler at his word that he wants to try to move the case to conclusion or near conclusion to the calendar year -- to the end of the calendar year.

To that end, we proposed this order. It really doesn't in and of itself contemplate discovery beyond the exchange of expert reports. And I would point out the obvious: That discovery in the strict sense has been closed. I'm at a loss to understand what discovery Ms. Brown is really contemplating.

So let me conquertize this. We know that the first trial, if you will, or disposition of cases are going to be in the economic track, not the bodily injury track. So if we take, for example, some grouping of defendants, say ZHP, and we know that one of the claims we briefed on certification and we intend to proceed on on liability is express warranty.

I would ask Ms. Brown what conceivable discovery do you need to move on that?

We're going to file a motion for summary judgment on that. We're going to believe there's both a factual and legal record upon which the Court can narrow the issues so that we can move forward with the trial of the case, subject, of course, to a cert ruling.

So what this order does is simply commit that to the calendar. And there's no prejudice or harm to Ms. Brown and the defendants by the Court entering this order. And if indeed there's some problem that I don't see today, it can be brought up to Judge Kugler, you know, at the end of the month. And if by some chance there needs to be a modification or addition to this order, we can always have another one.

But it's now been several weeks since the Judge ruled that this order should go in plus 60 days, and we would simply respectfully request it be entered today without prejudice to Ms. Brown and the defendants to raise any other issues which really don't appear to be very concrete today.

MS. BROWN: Your Honor, I believe the prejudice is enormous. I believe this is contrary to controlling law and would deprive us of our due process rights. I believe this order was the very order that was the subject of argument on June 1st, and I think the Judge was clear, and we cited the pages here, that they need to identify for us the state law. Counsel says he wants to move under express warranty.

What state law is going to control that, and what plaintiff is at issue?

And it sounds like counsel has in mind certain cases, certain laws, certain claims, Your Honor. And we would just respectfully request the opportunity to meet and confer on those and to understand what the cases are so that we too can

propose our own discovery that would be needed rather than a case management order that I would respectfully submit has already been discussed and Judge Kugler pointed out the deficiencies.

SPECIAL MASTER VANASKIE: All right. I'm going to issue this order. I'm going to sign the order that has been presented. I think, as I said before, you can fill in the details of this order.

Mr. Honik, you're going to be providing some additional information with respect to what the claims and under what state law you believe you will be moving, so you'll be providing that notice.

The order itself calls for dispositive motion -- deadline for dispositive motions in December of 2022. There's plenty of time to provide adequate notice with respect to what those claims are. Discovery is supposed to have been closed except for expert witness discovery. If there's a need to reopen it, that can be revisited upon the appropriate request.

MS. BROWN: And Your Honor, the --

SPECIAL MASTER VANASKIE: And I think it is important that this matter move forward with a schedule in mind. And I think this order accomplishes that.

Go ahead, Ms. Brown.

MS. BROWN: Thank you, Judge. I didn't mean to interrupt.

Could we just request that we identify a date by which they'll give us the information that it sounds like counsel has in mind.

MR. HONIK: Yeah. By the middle of next week, Your Honor.

SPECIAL MASTER VANASKIE: Okay. So today is the 13th. So we'll say by July 20th.

MR. HONIK: That's fine. Thank you, Your Honor.

SPECIAL MASTER VANASKIE: All right.

MS. BROWN: Thank you, Your Honor.

And with your permission, Your Honor, I'll hand the rest over to my colleagues, and if I could be excused.

SPECIAL MASTER VANASKIE: You may be excused. Thank you, Ms. Brown.

MS. BROWN: Thank you very much, Judge.

SPECIAL MASTER VANASKIE: Thanks.

The next issue I believe that should be taken up then is the question of the scope of core discovery for the losartan and irbesartan matters.

And are you addressing this, Mr. Honik?

MR. HONIK: I'm going to pass it off to Ms. Goldenberg, Your Honor.

SPECIAL MASTER VANASKIE: Okay, good.

Ms. Goldenberg?

MS. GOLDENBERG: Hi, Your Honor.

The good news is we only have a couple of very small issues for you. We had a couple of productive meet and confers leading up to this. And the starting point was the core discovery of course has already happened once. We don't need to relitigate all of the issues. And so we have agreed that all of the previous rulings on core discovery are, you know, very instructive as to where we go from here.

And really, the big issue that we need to talk with you about today is whether or to what extent defendants need to turn over testing results for nitrosamines in their pills.

In our mind -- you know, we've been in this court many times. We've been here for a few years already. And it seems like it's probably not a surprise that we would want testing levels for the pills that we haven't gotten testing results for yet.

And we did make it clear to defendants that when we saying testing results, we're not asking for all of the raw chromatography data yet, what we really want are the numbers. So what we want to know is how many nanograms or parts per million of nitrosamines are in these pills. And we have prioritized that with the understanding that the Court has ordered us to get our claims in order and to figure out what our priorities are.

So that's the ask. And I think I'll stop there for now.

SPECIAL MASTER VANASKIE: Okay.

And who is addressing this issue for the defense?

MR. BERNARDO: I am, Your Honor, Rich Bernardo.

SPECIAL MASTER VANASKIE: All right. Thanks, Mr. Bernardo.

MR. BERNARDO: And I appreciate Ms. Goldenberg's comments, and I agree. We've had a couple of successful meet and confers.

But I want to take a step back, because what might seem to be simple from Ms. Goldenberg's description really is anything but simple, and it's very burdensome, and we're just trying to put some reasonable parameters on it.

So just to sort of take a step back and recall, Your Honor, the purpose of core discovery -- and I'm just using the phraseology that was in the order back in '19 on core discovery -- talked about easily identifiable, relatively simple to retrieve and discrete. And the core discovery had certain parameters to it. And those were all spelled out in an order back in 2019.

When plaintiffs presented the core discovery for irbesartan and losartan, they added to that. And they added in a couple of material respects. They added something that just said all nitrosamine testing. They added additional production of FDA materials. And during the meet and confer, they further added to sales data.

Defendants are trying to be cooperative and come to some reasonable compromise here and agreed with respect to getting reasonably available sales data, agreed to providing additional FDA materials.

And I point out, Your Honor, that those were materials that I understand took substantial time to pull together and were done in terms of general discovery last time, but we agreed to do that.

We even agreed to say we will provide some amount of nitrosamine testing material, mindful of the fact that the defendants who have participated in discovery already provided anything pre-recall as part of the Court's order. But we pointed out that the nitrosamine testing was a significant burden in the valsartan period and took many, many months. It was the subject of -- and I think we spelled them out in our letter -- like two dozen different requests.

And I can't speak for the specific details of the burden for each defendant, but I can describe for Your Honor that it's not a push button, for example, for my clients. I spent time with them, and I understand it's something that literally needs to be manually compiled through hard copy material in correlation with data analyses they have.

Again, if it were something super easy, we wouldn't put up a philosophical blockade, but it isn't. It's something that's very, very detailed. And what we proposed to do as

just a compromise was to provide the nitrosamine testing for irbesartan and losartan as an initial offering that was provided to FDA. That certainly should be ample to provide plaintiffs the core type of information that they need, but we don't agree at this point in time going beyond that.

Plaintiffs in their letter say, well, you should have known this was coming. But actually, we shouldn't, because I think Judge Schneider was very, very specific in his prior rulings that discovery was about valsartan, in fact even made comments I saw in the transcript that he didn't think discovery in losartan and irbesartan would materially advance anything given the volume of what was produced on valsartan.

So, again, trying to be reasonable, trying to accommodate but needs some reasonable limits, because I will represent certainly not for ZHP -- and I've been told by my colleagues and the co-defendants, not for them either -- can they do what plaintiffs are asking for in 90 days. And it would require a significant burden.

SPECIAL MASTER VANASKIE: All right. Ms. Goldenberg?

MS. GOLDENBERG: Just a quick response to that, Your Honor.

I'm very glad that Mr. Bernardo brought up that this was the subject of multiple discovery requests, because, yes, we asked for it before, and I don't think it's a surprise that we were going to ask for it this time, so I don't think it was

a surprise that they -- that we would want the testing data. This is the core of all of the claims. And as plaintiffs' leadership, we've, you know, been tasked with the duty of working up these cases as to all three drugs. The fact that discovery was going to be coming and that we might need this information in order to ultimately resolve this MDL should not be a surprise to anyone.

And while core discovery at the beginning of this litigation was designed to be the easily accessible documents because everyone had just started, we've been here for almost three years now. And it is shocking I think on our side to think that the defendants wouldn't have figured out what their testing results were for these other two drugs that have been a part of this MDL for a long time now.

But as to how to retrieve it, again, it's wonderful that the defendants raised the RFPs, because they've already put together search methodologies to retrieve testing results in the past, and we anticipate that those same methodologies could be utilized here again.

And so we -- this is some of the most important information we could have in this case. It seems very difficult to believe that they couldn't produce this to us.

SPECIAL MASTER VANASKIE: Why --

MR. BERNARDO: I -- I'm sorry, Your Honor.

SPECIAL MASTER VANASKIE: Why isn't the production of

the testing data provided to the FDA sufficient, at least for -- at least initially?

MS. GOLDENBERG: We have already seen some different data come in from lower tier defendants in this case that differs from the testing -- the limited testing data that we have from the defendants on the losartan and irbesartan. And it's our understanding that there is a lot more that we don't have that wasn't turned over to the FDA.

We also found out at the beginning -- or sorry, in the valsartan portion of the case that there were testing data levels that materially differed from what was turned over to the FDA. And so now that we understand that those differences exist, we can't rely on what was turned over to the FDA.

MR. BERNARDO: And Your Honor, may I address two points that Ms. --

SPECIAL MASTER VANASKIE: You may.

MR. BERNARDO: Thank you, Your Honor.

I want to be clear, I'm not standing here, saying we're shocked that you're interested in nitrosamine testing, or, you know, that we haven't engaged in methodologies to identify that testing for valsartan that we can use here. What I'm saying is that what we're talking about here is core discovery, easily identifiable, relatively simple to retrieve and discrete.

Nitrosamine testing was never part of core discovery

for that very reason. And what I'm just describing is looking at the methodology that would need to be applied to losartan and irbesartan.

And this is for those defendants who already had engaged in discovery on valsartan. I want to remind the Court that there are defendants who would be responding to this who didn't do that. It's not something that can be done in a simple or short time frame, and it's not necessary for an immediate -- again, not saying never, not even saying, you know, when it would be, just saying not something to request within 90 days.

MS. GOLDENBERG: Your Honor, if I could just --

SPECIAL MASTER VANASKIE: Go ahead. Sure, Ms. Goldenberg.

MS. GOLDENBERG: I should also mention that the testing turned over to the FDA oftentimes was just about limited batches of losartan or irbesartan or, in the previous portion of the case, valsartan.

We have defendants in this MDL who did not recall all of their pills on the basis that they say not all of them were contaminated. And so when we are trying to evaluate the level of liability that might be assigned to a particular defendant in this case if what we have at the beginning is only limited testing data, it's not going to tell the full story.

SPECIAL MASTER VANASKIE: Is it correct that

nitrosamine testing results were not part of core discovery for valsartan?

MS. GOLDENBERG: It is correct, Your Honor.

MR. HONIK: Your Honor, may I add one thing just as a practical matter, which is not --

SPECIAL MASTER VANASKIE: Certainly, Mr. Honik.

MR. HONIK: I'm very mindful, and it's the remaining issue for today's conference, that we've been court ordered to mediation.

It's unimaginable to me that these defendants if they proceed, as I'm sure they will, in good faith to mediate with us, that they're going to want to mediate less than a global resolution of all claims.

I don't really know as a practical matter how a month from now we go into mediation without understanding what the levels of contamination were in losartan and irbesartan.

And so if for no other reason that than that, it seems to me critical to obtain that kind of core discovery, because what we're going to hear invariably is, well, we don't want to pay you X because our contamination was Y, or it didn't cover all pills, or what have you.

And in order for us to have a meaningful engagement, which I think the Court wants us to have, in understanding, as this MDL is about, all three, you know, drugs here, we really need to get our arms around what these levels were.

And so in many respects, we tailor our request with that in mind. And it's eminently reasonable, and recognizing as we do three years into this litigation the sometimes disparate results between what the FDA has and what the companies themselves have, it strikes me as eminently reasonable for them, that is, the defendants, to produce it.

If the issue is one of execution and they need more time or they need to do it on a rolling basis, we can certainly address that. We don't want to impose unfairly or unduly. But it seems to me seminal to advancing this case and being appropriately prepared for mediation, as I'm sure the Court wants us to be, to have these values.

MR. BERNARDO: Your Honor, and I appreciate Mr. Honik's comments, and I don't want to mince words. And to be clear, we here on this call for defendants and for plaintiffs are not part of this conference in late August. There are separate settlement counsel, as I'm sure Your Honor is aware.

SPECIAL MASTER VANASKIE: Right.

MR. BERNARDO: As I understand it, it is not a mediation, but again, I don't want to mince words, it is a settlement conference that was ordered.

But I reached out to our settlement counsel, and I asked my co-defendants who are participant as well to reach out to theirs, just to get a better understanding of this and

what plaintiffs are asking for here.

And what I heard from all of these folks through my colleagues, some of which are on this call, they're confused and they're not aware of any reason why the type of information that plaintiffs are seeking to accelerate here, particularly for an August conference that I understand is an initial conference, is really relevant and in fact thought at some level it could end up, you know, taking away the proper focus.

Having said all of that, a rolling basis and starting some in 30 days doesn't really help what I understand is the burden and the amount of time.

I mean, this took many, many, many months for valsartan to be produced. We are in the middle of the summer, when, as I'm sure Your Honor appreciates, many people, including the contacts that many of us would have at our clients to try and even begin to get this stuff, are unavailable for periods.

So again, I'm not -- I'm not disagreeing with providing this information. I'm sort of going back to your question, which is, is this part of core discovery, was it part of core discovery, and the answer is no. And if it is, we're willing to agree to some reasonable limitation.

We proposed what was provided to FDA. We got nothing back as an alternative. What we got back is literally the

words "all nitrosamine testing."

I'm not even sure I fully understand what that means. You know, any testing for all release testing done through, like, yesterday? So it's just -- it's the definition of an overly broad request that's at this point a fishing expedition. And it really can't be part of the core discovery, particularly while we're also trying to pull the other materials that are, we agree, part of core discovery and do those on a rolling basis in a methodical manner.

MR. HONIK: Judge Vanaskie, I know that you were not our master the entire duration of the litigation, but my memory is very clear that most, really all the defendants but one, got this material to us exceedingly promptly. We're not asking them to do testing now. This is testing that was already done that revealed levels which is stored somewhere.

The one and only defendant who took months to produce this did so because they decided to ship empty hard drives from India rather than do it from their computers. And I know Your Honor remembers that.

So, you know, just to be clear, I'm really at a loss to understand why it would take months. This information must exist somewhere in the defendants' current possession. And gathering that in some electronic way and sharing it with us so that we can meaningfully have this information, it's clearly relevant, and I say it's directly relevant to

evaluating the case. Whether next month is a settlement conference or a mediation, we're three-and-a-half years into the case, we just want the information. We think it's reasonable that we should have it now.

SPECIAL MASTER VANASKIE: Well, I understand that. But even under the core discovery order, there's no assurance you'll have it within -- before the end of August.

MS. GOLDENBERG: Your Honor, I can --

SPECIAL MASTER VANASKIE: You can do a rolling production --

Go ahead, I'm sorry.

MS. GOLDENBERG: Oh, I was going to say, Your Honor, we actually offered to defendants to prioritize our requests, because we recognized that there may be some issues in producing everything at once. So we had told them that the most important pieces of information for us were these nitrosamine testing levels and the sales data.

I understand that what I'm about to hear in response is that this is the most difficult thing to produce.

And obviously, you've heard already from us that we disagree with that for the reasons we've already articulated, but we have made an effort to prioritize our requests, because this is, as Mr. Honik already articulated, for mediation the most important piece of information that we can have.

MR. BERNARDO: Your Honor, I wouldn't be up here

making this argument, and at the risk of beating a dead horse, if this were pushing a button and easy to produce. And it's very easy for plaintiffs who don't have access to our client or their systems to say what is or isn't easy.

I can also represent my understanding, and I actually had a call with my clients two nights ago to go through this, because this was not a quick process for ZHP and took many, many months. I'm not sure what Mr. Honik is referring to in India. I suspect that's not ZHP. But I'm telling you that it was a lengthy process. And I don't know if Steve -- I don't see his name, I think he's on -- Harkins, you know, who lived through this or Victoria can confirm that, but it wasn't a quick process.

SPECIAL MASTER VANASKIE: Well, I understand it may not be a quick process, and it's not pushing a button and taking a printout, providing it or downloading it or sending it as a digital file, but it is essential to the case. The fact that it wasn't part of core discovery initially to me isn't critical. I believe ultimately it's going to have to be produced, and I think it would be appropriate to make it part of core discovery.

So I will require the production of the nitrosamine testing results. We're talking only about the results, not the underlying chromatograms, I take it. So I'll require that.

If you need additional time beyond the 90 days and can demonstrate why you need more than 90 days, certainly I'd be sympathetic towards it.

But let's make it part of core discovery, not a subset. A subset of it was already going to be a part of core discovery as a result of your meet and confers.

And I want to acknowledge and express certainly my understanding and appreciation of your efforts to work out agreements on these matters. And so you reached an agreement that at least the FDA, the results that went to the FDA would be produced, but I'm going to expand it beyond that, because ultimately it's going to have to be produced. And so --

And it does seem within -- it may not be easily retrievable, it may not be low-hanging fruit, but it is core. And I think efforts should be undertaken now to produce that data. So I will require that it be produced as part of the core discovery order.

MR. BERNARDO: May I ask -- thank you, Your Honor -- two follow-up items on that --

SPECIAL MASTER VANASKIE: Sure.

MR. BERNARDO: -- that are part of plaintiffs' letter.

As I'm hearing Your Honor, if it does become burdensome to pull all this together and get it out within 90 days, we can come back, raise our hands, maybe come back to

Your Honor.

Plaintiffs have asked for this to be produced within 30 days, and I can represent at least for my client -- and I'm sure others would have the same thing -- it cannot be produced within 30 days. We'll make efforts to prioritize it as Your Honor has requested.

And then the other piece of that is that there's some request in here, I forget what it was, to have a rolling production, be a weekly production.

Your Honor, that becomes actually counterproductive. Without getting into the details of how the vendors work and how you have to lock down things, doing something on a weekly basis is going to make it slower.

I mean, I don't see any need for any requirement of the interim period of production, but if something is required, maybe like a monthly or something like that would be appropriate. But to request a weekly is not how it's ever done in litigation like this for the very good reason that it becomes more time-consuming and more burdensome than trying to do it on some longer period of time.

We recognize -- and Ms. Goldenberg and I discussed this. We're not intending a rolling production to be, you know, a page in July, a page in August, and, you know, 20,000 pages in September. We understand that. But I don't think we need some management of what rolling means.

SPECIAL MASTER VANASKIE: All right. All right. That's understood. I would not require weekly rolling production. I will not require that all this testing data be produced within 30 days, but it will be part of the core discovery order.

I know, Ms. Goldenberg, this may not be timely insofar as the settlement conferences are concerned, but my experience with matters of this magnitude is that won't be the only settlement conference that is conducted. It will take some time.

And so the defense can get moving and producing this data, and it will be done within the parameters of the core discovery order. All right.

MS. GOLDENBERG: Understood, Your Honor.

One other issue that was mentioned in the letter, and it is just a small one and I don't think necessarily a matter for dispute, but we need to -- in an effort to be targeted, understand the relevant time period for each defendant so that we can focus our efforts. And we're just asking the Court to order the defendants to disclose to us what they view to be the contamination period within a week's time so that we can evaluate that based on the information we have and move forward accordingly.

MR. BERNARDO: Thank you for raising that, Marlene. I should have raised that as well. It was on my list.

But I think we're having a disconnect, Marlene and Your Honor. The contamination period was never something the defendants agreed would be the relevant period for discovery.

And what we did, and we provided a proposed order, we suggested that we abide by what Judge Schneider did, the process, which, as I understand it, was essentially the manufacturing period plus one, in other words, going back one year farther.

And while the defendants, you know, can certainly provide what that is, I don't know that doing it within a week is necessarily doable for everybody. It may be for ZHP, but it may not be for others, to sort of pin that down.

I suggest -- this isn't going to hold anything up. Nobody's going to, like, not do things while they're sorting that out. What I suggest is that the defendants provide that to Ms. Goldenberg. And if there are any disputes, we'll just make sure, like we did last time, they get resolved in advance of the next conference, or if they can't be resolved, they get addressed with Your Honor.

I don't see this as being a significant issue, but I just wanted to point out that we're not talking about the, quote/unquote, contamination period. I mean, that's an issue in the case. Right? What we're talking about is the period for relevant discovery. And we suggested that we do it the same way we did it for valsartan, which is spelled out in the

Macro Discovery Order 303 and the transcript that led to that, which is Document 302.

MS. GOLDENBERG: And as long as what you're referring to is the manufacturing period, meaning the entire time the product was manufactured, minus one year, I think we're fine.

MR. BERNARDO: Yeah. And again, I want to be careful, Marlene, not to speak for all the defendants. I mean, I know from ZHP's perspective and I know from others', that's fine. If other defendants have some unique issue, they'll raise their hand and let you know. But for ZHP and I know for some other defendants, we're fine doing it that way.

MR. HONIK: And for the record, it's the manufacturing period plus a year --

MR. BERNARDO: Right.

MR. HONIK: -- not minus a year.

MS. GOLDENBERG: Sorry, yes.

MR. BERNARDO: I'm sorry, I thought I said plus and Marlene said minus.

MR. HONIK: It's plus.

MR. BERNARDO: Yes. Agree.

MS. GOLDENBERG: Back in time. We agree.

MS. BERNARDO: One year prior, how about that?

SPECIAL MASTER VANASKIE: Right.

Now, do I have in a document submitted from plaintiffs a proposed core discovery order?

MS. GOLDENBERG: We will be happy to codify what was submitted to you -- I apologize, I heard an echo.

We will be happy to modify what was submitted based upon your rulings today and submit it to you.

SPECIAL MASTER VANASKIE: All right. Very well.

MR. BERNARDO: Marlene, I think that just is essentially tinkering with the nitrosamine testing. Correct?

MS. GOLDENBERG: I think that's right.

SPECIAL MASTER VANASKIE: I think that's right as well.

All right. Anything else for today?

I think there was something with respect to the settlement conferences or the mediation session.

Who will be addressing that?

MR. HONIK: Yes, Your Honor. We raised an issue pertaining to that.

The order directing the settlement conferences, the first of the two directs defendants ZHP, Mylan, Hetero, Aurobindo and their subsidiaries and affiliates to attend.

And to be sure, the way we've been thinking about these cases, Teva and Torrent is an affiliate and belongs there, in no small part because they used the API from ZHP. In Teva's case I think they also purchased Mylan API. But that's the groupings. Those are the manufacturers the way we've constructed and think about the case. And we just

wanted to clarify that both Teva and Torrent are invited to the first dance.

SPECIAL MASTER VANASKIE: And this matter was brought to Judge Kugler's attention. And it's my understanding that he's referred the issue to the settlement masters for their determination and leaving it up to them whether to include them at the -- invite them to the dance.

THE LAW CLERK: Judge Vanaskie, may I address that?

SPECIAL MASTER VANASKIE: Yes, Loretta.

THE LAW CLERK: Judge Kugler heard from the settlement masters last evening, and they are -- they have proposed not to include the finish dose manufacturers in this first settlement conference.

SPECIAL MASTER VANASKIE: All right.

THE LAW CLERK: Just to go forward with the API manufacturers as listed in the order.

MR. HONIK: Thank you for that clarification.

SPECIAL MASTER VANASKIE: Okay. Thanks, Loretta.

THE LAW CLERK: Sure.

SPECIAL MASTER VANASKIE: All right. Is there anything else then for today?

MR. HONIK: Nothing for plaintiffs, Your Honor. Thanks.

MR. STOY: Judge Vanaskie, very briefly, this is just Frank Stoy for Mylan and the defense group.

I just wanted to remind the Court that we do have a motion still pending related to some testing results for one of plaintiffs' experts, Dr. Najafi. We just wanted to make sure that hadn't sort of slipped through the cracks, so I just offer that PSA to the Court.

SPECIAL MASTER VANASKIE: All right. I thank you for the PSA. And we'll get moving on that.

Is there anything else then?

All right. We will issue CMO, Case Management Order, 28. I'll await receipt of a revised core discovery order that can be issued. And we'll see you all or talk to you all in a couple of weeks, I suppose okay.

RESPONSE: Thank you, Your Honor.

SPECIAL MASTER VANASKIE: Thank you all very much. Thanks. Bye-bye.

(Proceedings concluded at 4:51 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Ann Marie Mitchell, CCR, CRR, RDR, RMR
Court Reporter/Transcriber

15th day of July, 2022
Date

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